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TITLE: Randomized Trial of an Environmental Medicine Approach to Gulf War Veterans' Illnesses

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14. ABSTRACT Since we have been working for another full year to get institutional Review Board Approval for this project and have not yet succeeded, we have learned the extreme difficulty in getting IRB approval for a safe, relatively noninvasive therapy. We have also learned that there are multiple layers oreview, and that after each review there are extensive clarifications, revisions, and additional details requested.					
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INTRODUCTION:

The purpose of the research is to study the efficacy of an environmental medicine approach to Gulf War Veterans' Illnesses. The hypothesis to be tested is these illnesses result from a maladaptation to the chemical environment to which we are all exposed, as described by Selye and Randolph. The approach is to house ill veterans in an environmental control unit, to start them on a rotation diet after a brief diet, and to monitor them for symptoms from exposures to foods and airborne chemicals. Adjuncts include allergy testing using the provocative-neutralization technique, vitamin supplements, exercise, and sauna-detoxification.

BODY:

We are still working on the first task, which is to obtain Institutional Review Board approval for the study. Efforts to obtain Institutional Review Board (IRB) approval for this grant are still under way. After the award was made, the DOD IRB reviewed the IRB and requested revisions. After a second review, we were instructed to seek approval from the East Carolina University (ECU) IRB before further review by DOD. The ECU IRB reviewed the protocol in January 2008 and requested changes. These were made, and the ECU IRB approved the protocol in March 2008. The ECU attorney objected to the ECU IRB acting as IRB for the Environmental Health Center - Dallas (EHCD) even though the proper affiliation agreement had been signed, the ECU IRB was in agreement, and the researchers at Dallas had taken the necessary training. Hence, the EHCD had to become certified to have their own IRB, which required extensive paper work and more delays. The EHCD IRB met in May 2008 and approved the protocol. The protocol was then forwarded to the DOD IRB for final review. The DOD IRB required until September 2008 for their third review of the protocol. In September 2008 we received a 27 page document requesting extensive changes. To meet the multiple objections, the entire protocol has to be redesigned. The protocol then went

through another five month review by the DOD IRB, with another request for extensive changes to the protocol. These were made and returned to the DOD IRB. The DOD IRB informed us that another scientific review would be undertaken because of the changes that were necessary in order to meet many of the objections to the original protocol. How long this will take is below our control. The protocol is an environmental medicine approach to Gulf War Veterans illnesses. This approach involves housing in unpolluted air, a brief fast followed by a rotation diet, exercise and sauna, vitamin supplements, and allergy testing. This is a safe approach that has been used on tens of thousands of patients over the last fifty years. We hope that the protocol will be approved soon and we can begin the research. We hope that the IRB review process is not being used to block this research.

KEY RESEARCH ACCOMPLISHMENTS:

There are no key research accomplishments because we cannot begin the research until we obtain IRB approval to start the research.

REPORTABLE OUTCOMES:

None at this time because research cannot be conducted until the IRB is approved. After two years, the DOD IRB continues to review and re-review the protocol, requesting extensive changes and clarifications after each review.

CONCLUSION:

It is very difficult to get IRB approval for this project, requiring multiple reviews at multiple levels, each of which takes months, each of which requires extensive clarifications, revisions, and further review by three IRBs and scientific review of changes. We conclude that regulatory bodies can delay and block research for what seems like an indefinite period of time.